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PATENT

Customer No. 22,852

Attorney Docket No. 08888.0512

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Scherman *et al.*) Group Art Unit: 1632
Serial No.: 09/931,007) Examiner: L. Chen
Filed: August 17, 2001)
For: SYSTEM FOR REGULATING IN)
VIVO THE EXPRESSION OF A)
TRANSGENE BY CONDITIONAL)
INHIBITION)

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Commissioner for Patents and Trademarks
Washington, DC 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

This paper is responsive to the Office Action mailed October 1, 2002, which set a shortened statutory period for response of one month. In a separate petition, Applicants have requested and paid the fee for a two-month extension of time. Thus, the period for response has been extended until January 1, 2002.

The Office has issued a restriction requirement, asserting that pending claims 1-112 are directed to 15 allegedly separate and distinct inventions. Office Action, pages 2-6. Applicants are required to elect a group of examination on the merits. *Id.*, page 9. In response, Applicants elect Group III (claims 1-7, 9, 12, 13, 14-28, 30-39, 41-43 or 44-55, 57, 60-70, and 72-77) with traverse.

Additionally, for any of groups I-XII, the Office requires Applicants to elect a single species from among:



FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

(I) Inhibitory Transcript: an antisense RNA, an RNA capable of forming a triple helix with a portion of the nucleic acid, or a ribozymes.

(II) Method of introducing the nucleic acids into target tissue or cell: a physical/mechanical method, or a chemical/biochemical agent.

(III) Administration methods: systemically, or local (such as topically cutaneously) injection.

Office Action, page 6. Applicants elect, with traverse, species (I). Claims 1-7, 9, 12, 13, 14-28, 30-39, 41-43, 44-55, 57, 60-70, and 72-77 read on this single disclosed species.

In traversing the restriction requirement, Applicants draw the Examiner's attention to M.P.E.P. § 803, which requires that there be a serious burden in examining the claims without restriction. In the present case, the Examiner has not shown that there would be a serious burden to examine many of the groups together, despite the Office's contention that the inventions are distinct. For example, the Office contends, "Inventions I-XII are directed to patentably distinct inventions as they are different in composition." Office Action, page 7. Yet the Office has indicated that all of the claims in these 12 groups are identically classified in class 435, subclass 69.1. Certainly this indicates that the search of these groups together will not be problematic. According to the Office's own admission, the relevant art will be identified by searching a single subclass.

Also, the Office distinguishes the claims of groups I-XII because they recite different regulatory elements in conjunction with the claimed first and second nucleic acid sequences. Applicants contend that swapping various promoters, recognition sequences, *etc.* does not create an undue search burden on the Office. Such information (*e.g.*, types of different responsive promoters) may routinely be found in the

same publication. Thus, a search of group I would significantly overlap with a search of groups II, III, IV, *etc.* This is not burdensome. Thus, there is no reason why the Office should not search the full scope of Applicants' original claims. For these reasons, Applicants respectfully request that the restriction requirement be withdrawn, or alternatively, that the subject matter of groups 1-12 be rejoined into a single group for examination.

For similar reasons, the Office should also withdraw the election of species requirement. The Office has not established that there would be a serious burden in examining the nucleic acid composition claims (*i.e.*, inhibitory transcripts) with their claimed methods of use (*e.g.*, introducing the nucleic acids into a target tissue or cell by transfection techniques; administering by injection; *etc.*). The method of use claims employ the same compounds embraced by the composition claims. And Applicants contend that a search of art for the claimed compositions will also identify many methods of their use. Given such significant overlap in the search, there is not a burden on the Office to examine all of the claimed species together. Thus, Applicants respectfully request that the election requirement be withdrawn. In any event, if the Office finds the elected species allowable, the search must be expanded to include the other allowable species. M.P.E.P. § 803.

If necessary, please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: 

M. Todd Rands
Reg. No. 46,249

Dated: December 30, 2002

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com